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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,969	11/03/2003	Xiangsheng Zheng	5656-16DV	5022

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EXAMINER	
EVANISKO, GEORGE ROBERT	
ART UNIT	PAPER NUMBER
3762	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/699,969	ZHENG ET AL.	
	Examiner	Art Unit	
	George R. Evanisko	3762	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-9 and 11-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-9 and 11-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

In the rejections below, it is noted that the use of "distal", "intermediate", and "proximal" are relative terms and dimensions since no size has been set forth in the claims (or specification) as to the length, size, and/or location as to where these portions/sections are located.

Claims 1, 3-5, 11-15, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Rutten et al (6083247). Rutten shows in figures 1 and 2 the first catheter, 28, intermediate electrode, 36, with distal end connected through the connecting member (the ring in figure 2) to the intermediate section of the second catheter, 16. It is noted that the catheter is about 1 mm in diameter and therefore is capable of meeting the functional use recitation of being used for the coronary sinus.

Claims 1, 3, 4, 7-9, 11-14, and 17-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Bonner et al (5902331). Bonner shows in figures 5-9, the first catheter, 12, having an electrode, e.g. 34, and second catheter, 60', with connecting member, 71, connected to the

distal portion of first catheter and intermediate portion of second catheter. In addition, since the connecting member can be moved anywhere on the leads, it is capable of meeting the functional use recitations presented in the claims of locating it on the first distal portion and second intermediate portion (the same as the applicants releasable/retractable loops and elastic member). Bonner also describes for figure 8 how the system is used in the coronary sinus and his catheters are capable of being used in the coronary sinus or RV because of their small size. Finally, for claim 1, the electrode is connected to the intermediate portion through the lead body (it is noted that the claim does not state that the electrode is "located" in/on the intermediate portion).

Claims 1, 3-7, 11-17, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Morgan et al (5674274).

Morgan shows in figures 1-8 the use of a permanent or releasable connecting member, 66 (e.g. col. 4, lines 35-55), connected to intermediate portion of second catheter, 32, with first catheter, 40, having an intermediate electrode, 72. In addition, it is noted that although the second catheter has tines, it is still capable of being used in the coronary sinus and/or is of a size capable of being used in the coronary sinus.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6 and 16 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rutten et al. Rutten shows in figures 1 and 2 and describes how the first catheter is connected to the second catheter and is meant to be locked into place and used and therefore has a permanent connection.

In the alternative, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable system as taught by Rutten with a permanent connection since it would provide an implantable system with a permanent connection to allow the lead to be chronically implanted and fixed in the patient.

Claims 7-9 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rutten et al (or Morgan for claims 8, 9, 18, and 19).

Rutten (or Morgan) discloses the claimed invention except for the releasable connection, the retractable loop, or elastic connection. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable lead as taught by Rutten (or Morgan) with the releasable connection, retractable loop, or elastic connection since it was known in the art that implantable catheters use releasable connections, retractable loops, or

elastic connections to allow the catheter to be easily disengaged from one another for fast placement or removal from the patient and/or quickly engaged and moved relative to one another once the catheters are properly positioned.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-9, and 11-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 7020518 in view of Rutten, Morgan, or Bonner. The patented claims are narrower and meet the limitations of the broader application claims. In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the patented claims the use of an intermediate electrode, the catheters being used in the CS or RV, and the different connecting members, such as the loop, elastic, permanent members, in view of Rutten, Morgan, or Bonner

since such modification would provide a heart system for use in different areas of the heart to easily place and locate the catheters.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Osypka or Fujiwara are two examples of many showing the use of two catheters with a connecting elastic/retractable loop.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

George R Evanisko
Primary Examiner
Art Unit 3762
5/12/7

GRE
5/18/07